IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT STEVEN GOLDWASSER, M.D.

Plaintiffs respectfully request that this Court exclude or otherwise limit the opinions and testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Steven Goldwasser, M.D. ("Dr. Goldwasser"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Goldwasser is board-certified in Obstetrics and Gynecology, with a subspecialty board certification in Female Pelvic Medicine and Reconstructive Pelvic Surgery. *See* Exhibit B at 2 (Dr. Goldwasser's Expert Report). Plaintiffs do not challenge his qualifications as such. Dr. Goldwasser currently works at North Florida OB/GYN in Jacksonville, Florida. He obtained his medical degree from Tulane University School of Medicine, he completed his internship and residency at University of Tennessee, Memphis in the Department of Obstetrics & Gynecology, and he completed a fellowship as a clinical instructor of Urogynecology and Reconstructive Pelvic Surgery in the Department of Obstetrics and Gynecology at the Good Samaritan Hospital in Ohio. *See generally* Exhibit C (Curriculum Vitae). Additionally, Dr. Goldwasser serves as a paid consultant and professional education instructor for Ethicon. *See generally* Exhibits B and

D (Deposition of Steven Goldwasser, M.D., 7/1/17). Dr. Goldwasser has been hired by Ethicon to prepare a general report on the design, safety, and efficacy of the Gynecare TVT and TVT Exact polypropylene mesh midurethral slings. *See* Exhibit D 40:12-17.

In his General Report, Dr. Goldwasser's opines that both devices listed above have "been considered safe and effective as a surgical implant for over five decades." *See* Exhibit B at 26. Further, Dr. Goldwasser offers his opinions concerning the adequacy of Ethicon's IFUs ("Instructions for Use"), complications associated with these products compared to other surgical options to treat SUI conditions, outside opinions related to the design and performance of these products, positions statements concerning the safety of these devices made by Ethicon, professional societies, and the FDA, and the design and material properties of Ethicon's TVT and TVT-Exact midurethral slings. Moreover, Dr. Goldwasser opines that polypropylene sling products are the "gold" standard of care for treating stress urinary incontinence, and he offers opinions on the material properties of polypropylene mesh including degradation, cytotoxicity, mesh contraction, cancer rates, adequacy of pore size and weight of the mesh, and a lack of clinical difference between laser and mechanically cut mesh. *See generally* Exhibit B.

As explained below, Dr. Goldwasser is unqualified to offer opinions on the adequacy of Ethicon's IFUs and educational materials, as well as the design and scientific properties of midurethral slings because personal, clinical experience is not an adequate foundation for such testimony. Dr. Goldwasser's experience in the field of Obstetrics and Gynecology does not render all of his opinions admissible. Therefore, his opinions and testimony should be precluded or limited.

LEGAL STANDARD

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." F.R.E. 702. In the context of Rule 702, "'knowledge connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 590 (1993). Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the matters upon which she will opine are clearly within her area of expertise." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D. N.C. 2007).

If the expert is qualified, "[t]he U.S. Supreme Court [has] established a two-part test to govern the admissibility of [the] expert testimony under Rule 702—the evidence is admitted if it 'rests on a reliable foundation and is relevant.'" *Tyree v. Boston Scientific Corp*., 54 F. Supp. 3d 501, 516 (S.D. W. Va. 2014) (*quoting Daubert*, 509 U.S. at 597). Although "[t]he proponent of expert testimony does not have the burden to 'prove' anything to the court," he or she must nonetheless "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id*. (*quoting Md. Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided a non-exhaustive list of factors for a judge to consider in applying F.R.E. 702: "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4)

whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (*citing Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). "The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (*quoting Daubert*, 509 U.S. at 594-95). Even so, "'[e]xpert witnesses have the potential to be both powerful and quite misleading [;]' the [trial] court must 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Tyree*, 54 F.Supp.3d at 516 (quoting *Cooper*, 259 F.3d at 199).

ARGUMENT

I. Dr. Goldwasser's General Opinions Regarding the Adequacy of the IFUs and Professional Education Materials for the Gynecare TVT and TVT-Exact Polypropylene Mesh Midurethral Slings Should Be Precluded or Limited.

Dr. Goldwasser is not qualified to offer general opinions or testimony on the adequacy of IFU ("information for use") pamphlets or other Ethicon-made educational material because personal, clinical experience is not an adequate foundation for such testimony. Dr. Goldwasser gives no mention of his experience in designing IFUs or experience in selecting medical articles and peer-reviewed medical literature to include in IFUs. *See generally* Exhibits B and D. He even concedes that he does not necessarily look at product inserts for new drugs he prescribes. *See* Exhibit D, 72:24-25, 72:1. This concession should speak for itself: Dr. Goldwasser has no business opining on the adequacy of IFUs or educational materials because he does not even review an important component of the information himself.

Although Dr. Goldwasser states in his expert report that he has "reviewed and considered 21 C.F.R. 801.109(c),"[1] this statement lacks merit regarding whether Dr. Goldwasser is qualified to give opinions on the adequacy of the IFUs and educational material provided by Ethicon. *See* Exhibit B at 33.

Moreover, Dr. Goldwasser states numerous times throughout his deposition and in his general report that he bases many of his opinions regarding propylene mesh midurethral slings on his clinical knowledge and his experience as a paid Ethicon educational instructor. *See* Exhibit D, 58:25, 79:4-9; *See* Exhibit B at 32. As this Court has previously held, medical experts are not qualified to offer opinions regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience. *See Sederholm v. Boston Scientific Corp*., C. A. No. 2:13-cv-12510, 2016 WL 3282587 at *13 (S.D.W.Va. June 14, 2016) (excluding urologist's expert opinions on the adequacy of defendant's IFU that he based solely on the risks he observed in his practice.).

Continuing on, Dr. Goldwasser has given no indication or proof of familiarity with the standards applicable to medical device IFUs, the industry standards governing warnings on medical devices, or the process by which IFUs are developed and approved. *See* generally Exhibit D. A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. General Motors Corp*., 190 F.3d 244, 250 (4th Cir.1999). Relevant and compelling medical literature was absent from not only Dr. Goldwasser's expert report, general reliance list, and supplemental reliance list, but also Ethicon's IFU's and peer-

[1] This statute states that risk information for devices used by licensed professionals may be omitted from product labeling if the "article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. 801.109(c).

reviewed medical literature given to Dr. Goldwasser as a paid consultant to give expert opinion on their TVT and TVT-Exact devices.

In his deposition, Dr. Goldwasser states that when he was forming his opinions about the safety and efficacy of the TVT and TVT-Exact slings, he reviewed and relied not only on his personal, clinical experience, but also on the peer-reviewed medical literature that Ethicon provided to him regarding these slings:

> A Well, I'm not exactly sure what the supplemental one is, but the general reliance list, excuse me, is -- is the literature that was available to me to look over and review as part of the preparation of writing the report.
>
> Q Is it a list of materials for you to look over in preparation for your report that you relied upon that was given to you or is this something that you've created and found the articles, added the articles yourself?
>
> MR. RUMANEK: Object to the form.
>
> A combination of the two.

See Exhibit D, 37:2-13.

This is problematic because, as stated above, Ethicon failed to include many pertinent and relevant peer-reviewed medical articles in the IFUs, educational materials, and Dr. Goldwassers' general reliance list that discussed numerous aspects of the TVT and TVT-Exact slings, including incidences of adverse events. For example, in his expert report, Dr. Goldwasser cites a 17-year follow up prospective case series of 90 women receiving TVT mesh.[2] *See* Exhibit B at 3. However, as highlighted during his deposition, this study actually encompassed only 58 women due to various "drop-out" reasons. This study was also a prospective case series,

[2] C.G. Nilsson et al, *Seventeen Years' Follow Up of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence*, 24, Int'l Urogynecol J, 1265-69 (2013).

which Dr. Goldwasser states is the "weakest of epidemiological evidence" along with expert opinion. See Exhibit D, 56:3-6. Finally, and most importantly, the authors of this study noted a "conflict of interest" with various pharmaceutical and medical device companies, including Ethicon, because they had at one time or another been consultants for such companies, and medical journals now require authors to disclose this information due to concerns of bias. *See* Exhibit D, 61:1-7. While Dr. Goldwasser relied on this study in forming his opinions on TVT and TVT-Exact slings, he failed to analyze, and Ethicon failed to provide, a relevant and compelling article documenting a randomized controlled trial that described surgical complications in 597 women over a 24-month period following randomization to retropubic (TVT) and Transobturator midurethral slings.[3] *See* Exhibit D, 74:13-21, 76:1-6. This study's design fit the "gold standard" of epidemiological studies, the authors had no ties to Ethicon, and the study contained incidence rates for "serious adverse events" associated with the use of TVT and TVT-Exact slings. Why this article failed to appear in Dr. Goldwasser's "expert report" and Ethicon's educational materials is highly questionable.

As a side note, Dr. Goldwasser even concedes that he is unaware what the "supplemental reliance list" actually is; thus, it is difficult to know for sure that Dr. Goldwasser even understands what the "general reliance list" is. *See* Exhibit D, 37:1-6. This fact emphasizes that Dr. Goldwasser is unqualified to offer opinions regarding the educational materials given to him by Ethicon because he does not fully understand what was given to him and for what exact purpose.

Moving forward, Dr. Goldwasser states that he believes IFUs need not contain "incidence rates" of all adverse events because the need to know is "all in the context of the incidence;" if it

[3] L. Brubaker et al, *Adverse events over two years after retropubic or transobturator midurethral sling surgery: Findings from the Trial of Midurethral Slings (TOMUS) study*, 205, Am J Obstet Gynecol, 5, 498.e1-6 (2011).

is a "known," or common, adverse event that is to be expected, it is not needed in the IFU. *See* Exhibit D, 71:18-23, 78:17-25. However, Dr. Goldwasser lacks any and all qualifications to assert such statement because he is of the opinion that if the adverse event lacks "serious ramifications," it is "inconsequential clinically." *See* Exhibit D, 80:9-19. Definitions of "serious" can vary from person to person and doctor to doctor, *see* Exhibit D, 79:21-25, 80:1-3, so Dr. Goldwasser cannot speak for the entire Obstetrics and Gynecology community when he states that IFUs do not need to contain incidence rates of adverse events. Moreover, he stated in his deposition that he is unaware of the obligations placed on pharmaceutical companies or medical device companies, with regards to their duty to report adverse events, to send such reports to the FDA, and he is unaware that the total number of adverse events reports to the FDA and pharmaceutical companies is available in the medical literature. *See* Exhibit D, 66:23-25, 67:1-6, 69:15-23.

To conclude, every piece of evidence listed above lends itself to showing that Dr. Goldwasser is unqualified to speak to the adequacy of Ethicon's IFUs and educational materials. Dr. Goldwasser has failed to offer this Court sufficient proof that the adequacy of IFU material is within his area of expertise. Specifically, in his deposition, he states that he is more likely to pull up a report or article, or even general information on a medical device, on the Internet than he is to read the IFU:

> 23 Q. And have you seen in any IFU or that --
> 24 has any representative for Ethicon informed you that
> 25 with their device, there was a 77 percent increased
> 1 risk of a serious adverse event based upon a
> 2 randomized controlled TOMUS study?
>
> 3 MR. RUMANEK: Object to the form.
>
> 4 A. I would say that this information's
> 5 readily available to any physician who wants to find

> it. And so I think it's available, it's not hidden.
>
> Q. It's available if one goes searching for it versus picks up the IFU, which comes with the device, correct?
>
> MR. RUMANEK: Object to the form.
>
> A. But you don't necessarily have the IFU before you're doing the -- you know, you're – the IFU is in the box, okay. So if I'm in my office and I don't know something, it's a lot easier for me to go pull it up -- a report rather than go find the box. You know, in terms of readily available, I think it's just as readily available as any of this.

See Exhibit D, 82:23-25, 83:1-18.

Therefore, due to the fact that Dr. Goldwasser's opinions regarding what he would consider to be an adequate IFU are based primarily on his personal clinical experience, and that he readily concedes he does not use them often, his opinions concerning the adequacy of the TVT and TVT-Exact Midurethral Sling IFUs and Ethicon's educational materials and information are unreliable and should be excluded.

II. Dr. Goldwasser's General Opinions on the Design and Scientific Properties of the TVT and TVT-Exact Midurethral Slings Should Be Precluded or Limited.

Dr. Goldwasser is not qualified to offer general opinions or testimony on the design and scientific properties of TVT and TVT-Exact midurethral slings because personal, clinical experience is not an adequate foundation for such testimony. Dr. Goldwasser lacks any specialized education, training, or applicable relevant experience specifically related to the design of polypropylene mesh devices. *See generally* Exhibits B and C. In fact, Dr. Goldwasser concedes that he is not an expert in designing mesh devices and has limited knowledge of the design process:

17 Has Ethicon ever approached you about
18 designing for them an animal study to look at
19 polypropylene mesh?

20 A No.

22 Q. Have they ever approached you to and
23 consulted with you -- have they approached with you,
24 consulted with you, asking you to design any form of
26 polypropylene mesh to be used in women?

27 A No.

See Exhibit D, 31:17-25.

Notwithstanding Dr. Goldwasser's admission that he is not an expert in designing mesh devices; notwithstanding the fact that none of his five peer-reviewed publications pertain to mesh; and notwithstanding the fact that, although Dr. Goldwasser has a "provisional patent" for a reconstructive pelvic surgery device (the Exair), he never conducted Phase 3 clinical trials with this device, it is no longer available in the United States due to "product demand," and there has never been anything published about this device in the peer-reviewed medical literature, *see* Exhibit D, 117:19-20, 118:12-15, 16-21, he attempts to opine on the design and material properties of the specificities of the TVT and TVT-Exact slings. His opinions include topics regarding degradation, cytotoxicity, mesh contraction, the appropriate pore size and weight of mesh, and the lack of difference between mechanical and laser cut meshes. *See* Exhibit B at 25-31. Specifically, his opinion in this regard is that the devices are "safe" and the gold standard for treatment of female stress urinary incontinence. *See* Exhibit B at 5. These opinions undoubtedly exceed the bounds of his qualifications.

First, with regards to degradation, Dr. Goldwasser is aware of conflicting viewpoints regarding degradation, but he strongly asserts that his "clinical experience and analysis of the body of data … supports [his] opinion that Ethicon's polypropylene mesh does not degrade in

vivo, or if it does, that such degradation does not have any clinically significant effect." *See* Exhibit B at 29-30. As with all other testimony, Dr. Goldwasser cannot render opinions on mesh degradation for two reasons: one, he has only ever removed "no more than 20" mesh devices from a woman in his 20+ years of practice, and only approximately **four** of which were TVT or TVT-Exact slings; and two, he does not recall if he has ever filed a report with the FDA for **any** adverse event associated with mesh, and he concedes that he is not an expert in the field of pathology or material sciences, which familiarity with either discipline would aid in knowing if any of his patents experienced mesh degradation. *See* Exhibit D, 29:21-24, 30:22-25, 88:11-17, 89:12-14.

The pertinent question to this analysis is not whether or not Dr. Goldwasser is right or wrong. Plaintiffs do not need to challenge these opinions based on their accuracy. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct). As is evident, Dr. Goldwasser did not rely on a valid scientific methodology in reaching his conclusions. Although Dr. Goldwasser claims to have reviewed the medical literature related to degradation that he found on his own, or that Ethicon provided to him, he admits that his personal research merely involved a "pick and choose" process:

> 1 How did you find each article that's listed in your
> 2 expert report, your general reliance report, your
> 3 supplemental report?
>
> 4 A Well, when I was doing a literature
> 5 search, I would look up certain topics, come across
> 6 articles, review them, see if it was something I
> 7 wanted to include in my report, and if so, it would
> 8 wind up in the reliance list. So it was a -- just a
> 9 process.

See Exhibit D, 46:1-9.

As this Court has observed, "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree*, 54 F.Supp.3d at 520 (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y 2005) (quotations omitted)). Where, as here, the "relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" *Id.*

Interestingly, Dr. Goldwasser states that he is relying on the 900+ articles in his General Reliance List to support his opinions on the safety and efficacy of the TVT and TVT-Exact midurethral slings, but he also concedes that not every article in his General Reliance list supports his opinions. *See* Exhibit D, 41:5-8, 44:7-8. It became clear that no one would be able to identify which articles he did rely on and which ones he disagreed with without going through every document. *See* Exhibit D, 43:13-21. This hinders one's ability to ensure his methodology for forming his opinions is sound and reliable. Under *Daubert*, a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation." *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method.)

Therefore, Dr. Goldwasser cannot offer opinions on mesh degradation because he has no foundation, other than his personal clinical experience, to stand on.

Next, with regards to cytotoxicity and cancer rates, Dr. Goldwasser contends that he is "not aware of any evidence that polypropylene, when used as designed for its intended purpose

as a mesh implant or as a suture material, has any clinically significant cytotoxic or cancer-causing effect." *See* Exhibit B at 30. He also asserts that "[c]ommon sense would dictate that based on the amount polypropylene material used in a surgical setting since its development in the 1950s, if there was a clinically significant problem, it would be a worldwide catastrophe at this point." *Id.* at 30-31. This statement lacks merit because Dr. Goldwasser has not evaluated every peer-reviewed medical article relating to cytotoxicity or carcinogenic effect, and he cannot use the fact that he has not personally seen it as proof that it does not occur.

As stated above, Dr. Goldwasser is unqualified to offer opinions on cytotoxicity or the carcinogenic effects of polypropylene mesh material because he does not hold himself out as an expert in gynecological oncology, he did not receive any training in gynecological oncology, and he has no formal training in material sciences. *See* Exhibit D, 15:5-8, 30:1-4. Dr. Goldwasser states that "[t]here is no reliable data demonstrating an association between mesh placement with subsequent cancer formation." However, he focuses heavily on "placement" of the mesh device, rather than the propylene mesh material itself. "Dodging" an issue does not indicate reliability and expertise.

Therefore, Dr. Goldwasser cannot offer opinions on mesh cytotoxicity and carcinogenic effects because he has no foundation, other than his personal clinical experience, to stand on.

To continue, Dr. Goldwasser offers opinions related to mesh contraction and the appropriate pore weight and size. As emphasized throughout, Dr. Goldwasser is unqualified too render such opinions. In his report, Dr. Goldwasser states "[i]n my practice, I have not seen a single case of contraction, and I am not aware of any literature that describes contraction associated with TVT or TVT-Exact." Exhibit B at 27. Further, Dr. Goldwasser states that pore size "can impact infectious risk and tissue integration." Exhibit B at 9. However, as stated

above, Dr. Goldwasser is not trained in material sciences, he has never designed a mesh device or been involved with the design process of a mesh device, and he cannot use the fact that he has never seen something or he has not read any literature describing something as dispositive that it does not occur or is not available. The United States Supreme Court, the Fourth Circuit and this Court have all expressly held that an opinion based on nothing more than the *ipse dixit* of the expert is inadmissible. *See,* e.g., *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* [an assertion made but not proved] of the expert"); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202-03 (same); *Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 499 (S.D.W. Va. 2002) (same); *see also Hoffman v. Monsanto Co.*, No. 2:05-CV- 00418, 2007 WL 2984692, *4 (S.D.W. Va. Oct. 11, 2007) (excluding an opinion that was based on "simply a subjective, conclusory approach that cannot reasonably be assessed for reliability") (quoting Fed. R. Evid. 702, advisory committee' s note (2000)).

Therefore, Dr. Goldwasser cannot offer opinions on mesh contraction and appropriate pore weight and size because he has no foundation, other than his personal clinical experience, to stand on.

Lastly, Dr. Goldwasser attempts to opine on the lack of clinical distinction between mechanically cut and laser cut mesh devices. Dr. Goldwasser asserts that

> "prior to modifying the production process Ethicon subjected the new laser cut mesh to rigorous testing and found that the mechanical properties did not result in any clinically significant differences. They were ultimately able to establish that changing the production process did not change the essential characteristics of the laser cut mesh. In my practice I have not noted any difference in clinical results between the laser cut mesh and the mechanical cut mesh. I have no preference between the two."

Exhibit B at 28.

However, Dr. Goldwasser did not reference any article or literature discussing different methods of "cutting" mesh, nor did he give any indication as to where this information came from. Once again, Dr. Goldwasser cannot offer opinions on the difference between mechanically cut and laser cut mesh devices because he has no foundation, other than his personal clinical experience, to stand on. Dr. Goldwasser's qualifications as a physician, even a physician specializing in pelvic reconstructive surgery, are insufficient to allow him to testify on design issues such as this. *Tyree*, 54 F. Supp. 3d at 559-560 (this Court excluded opinions by Dr. Jerry G. Blaivas, one of the plaintiff' s experts, relating to the design of pelvic mesh products).

In sum, Dr. Goldwasser's testimony and opinions on TVT and TVT-Exact midurethral slings should be precluded or limited for many reasons pertaining to his lack of qualifications:

First, with regards to the design of the TVT and TVT-Exact slings, Dr. Goldwasser concedes that he was unaware that both slings were approved based on a predicate device: The Boston Scientific Protogen device. *See* Exhibit D, 63:9-13. However, the Scientific Protogen device was recalled in 1999, and Dr. Goldwasser has not studied the adverse events report for the Scientific Protogen device "in preparation for being an expert regarding TVT and TVT-Exact. *See* Exhibit D, 64:5-9. Dr. Goldwasser even concedes that he does not recall the similarities between this predicate device and the TVT and TVT-Exact slings. *See* Exhibit D, 64:10-16.

Second, it was evident in his deposition that Dr. Goldwasser is biased against "attorney advertising" for transvaginal mesh litigation after a good number of devices were recalled from the market:

13 Q Now, I'll represent to you that each
14 withdrawal was followed by news stories, both on
15 television and in newspapers, which we can find on

16 Google.

17 A Sure.

23 Q How do you rule out your patients hearing
24 of these withdrawals on television and in the print,
25 or internet these days, and that being the source of

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1 "the wave of anxiety," as you write, versus lawyer
2 advertising?

3 A Because I think it's the advertising that
4 came first that led to -- you know, legal
5 advertising that came first that led to patient fear
6 over this that sort of spirals into lack of use of
7 the products that leads to news stories and so on
8 and so forth. So one begets the next.

See Exhibit D, 97:18-25, 98:1-8.

Dr. Goldwasser further states that he has observed in his clinical practice, as well as read three articles describing, a 30% decrease in patients "undergoing stress incontinence and pelvic reconstructive surgery." *See* Exhibit D, 99:6-25, 100:20-25. Dr. Goldwasser states that he bases this decrease on "patient fear" from "lawyer advertising." *See* Exhibit D, 101:5-12. However, he concedes that he has not done a formal study on the number of his patients foregoing TVM as a treatment option for SUI conditions, and he does not include in his expert report that "patient fear" is multifactorial.[4] *See* Exhibit B at 3; *See* Exhibit D, 99:5. Finally, even after the FDA issued its Public Health Notification Update in 2011 to "[h]ealthcare providers who implant surgical mesh to repair pelvic organ prolapse and/or stress urinary incontinence," to inform that "serious complications associated with surgical mesh for transvaginal repair" are **not** rare, *see* Exhibit D, 108:1-8, 109:18-24, Dr. Goldwasser maintains that lawyer advertising of TVM is the primary culprit for a decrease in his patients undergoing stress incontinence and pelvic

[4] Colby Perkins et al, *The Role of Mid-Urethral Slings in 2014: Analysis of the Impact of Litigation on Practice*, 10, Current Bladder Dysfunction Reports, 1, 39-45 (2015).

reconstructive surgery. The emphasis Dr. Goldwasser placed on lawyer advertising as the sole influence for patient fear is misplaced and inaccurate:

Q Now, Dr. Goldwasser, this article reviewed newspapers' articles.

A Uh-huh.

Q There's not a single description of lawyer advertising in this reference that you provide as support for your expert statement that lawyer advertising by self-serving lawyers has led to this wave of anxiety, correct?

MR. RUMANEK: Object to form.

A No, because it talks about mesh-related litigation.

Q It talks about newspaper articles about the litigation, not lawyer advertising.

MR. RUMANEK: Object to the form.

A It's not specifically talking about lawyer advertising, but it encompasses advertising as part of that news reports.

Q Sir, if we go back to the methods, they search two national newspaper databases.

A Right.

Q They pulled the articles about ongoing

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litigation.

A Right.

Q I've read this very carefully, there's not a single mention in here of television legal advertising at all.

A Well, I don't know that that is in those articles. I mean, mention -- I mean, yeah, it

8 doesn't specifically say, you know, legal
9 commercials here, but it's about the whole crux of
10 litigation regarding this whole topic.

See Exhibit D, 113:5-25, 114:1-10.[5]

Dr. Goldwasser referenced this article in his expert report, but he failed to include the parts of the study that negated his belief that lawyer advertising was the main reason for a "30%" decrease in his patients seeking surgical treatment for SUI conditions. As stated above, a "pick and choose" process renders a physicians' testimony unreliable. *See Tyree, supra*.

This evidence fully lends itself to showing that Dr. Goldwasser is undoubtedly unqualified to give "expert" opinions and testimony on the design and material properties of the TVT and TVT-Exact midurethral slings. Therefore, his opinions are unreliable and should be excluded.

CONCLUSION

For these reasons, Plaintiffs ask that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Goldwasser. Plaintiffs further request all other relief to which they are entitled.

Dated: August 15, 2017

Respectfully submitted,

/s/ D. Renee Baggett

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[5] Kevin Koo & E. Ann Gormley, *Transvaginal Mesh in The Media Following The 2011 U.S. Food and Drug Administration Public Health Notification Update*, 36, J Neurourol & Urodyanmics, 2, 329-332 (2015).